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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/079,758	05/15/98	MORRISON D	MSC-22939-1-

HM22/0616

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EXAMINER	
SHAREH, S	
ART UNIT	**PAPER NUMBER**
1616	3

DATE MAILED: 06/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/079,758	Applicant(s) Morrison et al
	Examiner Shahnam Sharareh	Group Art Unit 1616

☒ Responsive to communication(s) filed on *May 15, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-71* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-71* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-43, and 69-71, drawn to microcapsules used as therapeutic agent, classified in class 424, subclass 489.

   II. Claims 44-59, drawn to a method of drug delivery utilizing an energy source, classified in class 514, subclass 963.

   III. Claims 60-67, drawn to a method of treating a tumor by applying a magnetic field to the body, classified in class 600, subclass 9.

   IV. Claim 68, drawn to microcapsules prepared by a formulation process, classified in class 427, subclass 213.3.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I or IV and II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case a neoplastic tumor can be treated by other means of therapy such as non-microcapsulated neoplastic agents. Similarly, a drug may be delivered to a site of action by other methods of delivery such as methods using a PH-activated system as described by Klaveness et al WO 92/17212.

3. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the microcapsules of Group I can be prepared by other methods of preparations such as coacervation described by Baker et al US Patent 4,808,408 or known methods such as sonication. Therefore, the compositions prepared by these methods are distinct both physically and functionally, and require different process steps, reagents and parameters.

4. The mentioned inventions are distinct for the reasons given above. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious the any of the other groups. Therefore, restriction for examination purposes as indicated is proper.

Election of species

5. Claims 1-71 of this application are directed to the following patentably distinct species of the claimed invention: various energy absorbing medium such as graphite, aluminum powder or sodium amyl alcohol; various outer polymer shell such as glycerol monosterate, cholesterol, lecithins, or polyvinyl alcohol; various anti-cancer drugs such as cis-platin, vinblastine, tamoxifen, or bleomycin; various antibiotics such as penicillin, vancomycin, erythromycin, isoniazid or

gentamicin; various antifungal agents such as nystatin, or amphotericin; various antiviral agents such as idoxuridine, riboviran or amantidine, various drug or drug precursor agents such as hormones, metal poisoning antidote, cytotoxic agent, or a CT scan enchancer. The above mentioned species are considered to be independent since they are unrelated in operation, one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Mr. James M. Cate on June 7, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Shahnam Sharareh whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

Shahnam Sharareh, PharmD

S. MARK CLARDY
PATENT EXAMINER
GROUP ~~1200~~ 1616

acting SPE